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Laura Giles

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# PROMOTING GENERIC DRUG AVAILABILITY: REFORMING THE HATCH- WAXMAN ACT TO PREVENT UNNECESSARY DELAYS TO CONSUMERS

LAURA GILES<sup>†</sup>

## INTRODUCTION

The cost of prescription drugs has skyrocketed in the past decade.<sup>1</sup> The increase is partially attributed to the costs associated with the extensive research a drug must undergo before it can be made available to consumers.<sup>2</sup> As a result of these price increases, many consumers can no longer afford vital prescription drugs.<sup>3</sup> Furthermore, generic drugs, which are less expensive than their brand name counterparts, are taking a

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<sup>†</sup> J.D. Candidate, June 2002, St. John's University School of Law; B.A., Hofstra University.

<sup>1</sup> See Michael B. Moore, "Open Wide (Your Pocketbook That Is!)" – A Call for the Establishment In the United States of a Prescription Drug Price Regulatory Agency, 1 SW. J. L. & TRADE AM. 149 (1994) (citing the STAFF OF SENATE SPECIAL COMM. ON AGING, 103D CONGRESS, 1ST SESS., EARNING A FAILING GRADE: A REPORT CARD ON 1992 DRUG MANUFACTURER PRICE INFLATION 1 (Comm. Print 1993) (stating that there is a 128.4% inflation rate for pharmaceuticals versus 21.7% for general overall inflation)). The author predicted that if this rate of inflation continued, a drug costing \$20 in 1994 would cost \$120 dollars in 2000. *Id.* In general there is a fifteen percent annual rise in drug prices. See *Let Drugmakers Compete; Suffering the Most are Those Chronically Infirm Without Insurance That Covers Drugs*, MIAMI HERALD, Aug. 22, 2000. The United States is the last free market for pharmaceuticals. This means that Americans typically pay higher prices for new medication than people anywhere else in the developed world. See Sheryl Gay Stolberg & Jeff Gerth, *Keeping Down the Competition; How Companies Stall Generics And Keep Themselves Healthy*, N.Y. TIMES, July 23, 2000, at 1.

<sup>2</sup> See generally Joseph P. Reid, Note, *A Generic Drug Price Scandal: Too Bitter A Pill for the Drug Price Competition and Patent Term Restoration Act to Swallow?*, 75 NOTRE DAME L. REV. 309, 330–31 & n.126 (1999) (discussing the reasons that research and development costs are continually increasing).

<sup>3</sup> See Stolberg & Gerth, *supra* note 1. The couple profiled in the article is on an income fixed at \$1,261 a month in Social Security benefits. The cost of their prescription drugs is \$148 a month. The cost of the prescription drugs amounts to one-tenth of their income and imposes considerable financial hardship on the couple. *Id.*

longer time to become available and are facing dramatic price increases.<sup>4</sup> Is there any way that a drug company can perform its research while keeping market prices lower? Perhaps.

The purpose of this Note is to explore some of the obstacles that pioneer pharmaceutical companies create to prevent generic pharmaceuticals from getting to the market. The pharmaceutical companies' tactics include patent infringement suits and secondary patents, pioneer acquisition of generic drug companies, and collusion between pioneer companies and generic companies to keep generic drugs off the market. This Note will examine the drug approval process for both pioneer and generic pharmaceuticals, with a particular focus on the Hatch-Waxman Act<sup>5</sup> (the "Act"). Finally, it will examine possible reforms in the pharmaceutical industry that may prevent companies from engaging in these tactics.

## I. DRUG APPROVAL PROCESS

### A. Pioneer Approval Process

The approval process for a new drug is extremely time consuming.<sup>6</sup> No new drug may enter the U.S. market without approval from the Food and Drug Administration (FDA) as to its safety and efficacy.<sup>7</sup> The process begins after a drug manufacturer has completed an initial laboratory research

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<sup>4</sup> In 1998, generic drug prices increased 3000%. See *Definitely a Cause of Anxiety*, L.A. TIMES, Dec. 24, 1998, at B8.

<sup>5</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 15 U.S.C. §§ 68b-68c, 70b (1994); 21 U.S.C. §§ 301, 355, 360cc (1994); 28 U.S.C. § 2201 (1994); 35 U.S.C. §§ 156, 271, 282 (1994)).

<sup>6</sup> See Richard J. Findlay, *Symposium Issue—Striking the Right Balance Between Innovation and Drug Price Competition: Understanding the Hatch-Waxman Act: Originator Drug Development*, 54 FOOD & DRUG L.J. 227, 227 (1999) (noting that the entire approval process can take fourteen to sixteen years but is subject to substantial variability). The Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 (2000), governs the new drug approval process.

<sup>7</sup> See 21 U.S.C. § 321 (1994); see also Patricia I. Carter, *Federal Regulation of Pharmaceuticals in the United States and Canada*, 21 LOY. L.A. INT'L & COMP. L.J. 215, 229 (1999). See generally 21 U.S.C. § 355(b)(1)(A); 21 C.F.R. § 56. "Prior to 1962, drugs were approved for safety only"—there was no efficacy requirement. Gerald J. Mossinghoff, *Symposium Issue—Striking the Right Balance Between Innovation and Drug Price Competition: Understanding the Hatch-Waxman Act, Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999).

program that can take thirty to fifty-seven months to complete.<sup>8</sup> If the pioneer company believes that the pre-clinical testing shows that the drug may help to treat a certain condition, it may "sponsor" the drug and file a Notice of Claimed Investigational Exemption for a New Drug (IND) with the FDA.<sup>9</sup> If there is no objection from the FDA, the drug is labeled "investigational new drug" and clinical trials may commence thirty days after filing.<sup>10</sup>

The approval process has four phases.<sup>11</sup> Three of these phases are completed during the clinical testing period. The three phases of clinical testing can often take up to nine years.<sup>12</sup> Once these three phases have been completed the pioneer company or "sponsor" submits a New Drug Application (NDA).<sup>13</sup> "The NDA has become the principal regulatory device for controlling pharmaceutical companies in the United States."<sup>14</sup> The NDA requires that the sponsor provide extensive documents demonstrating the safety and efficacy of the drug.<sup>15</sup> The FDA thoroughly reviews these documents for "clinical, chemical, statistical, and pharmacological" evidence that the drug is effective and safe.<sup>16</sup> A "full review can take years."<sup>17</sup>

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<sup>8</sup> See Findlay, *supra* note 6.

<sup>9</sup> See Carter, *supra* note 7, at 231. ("This IND application provides notice that clinical (human) trials will be conducted, contains information about the pre-clinical results, outlines the proposed clinical studies, identifies experienced clinical investigators who will conduct the trials and provides other information about the manufacturing and testing processes.")

<sup>10</sup> See *id.* at 230-31. Clinical trials essentially mean that a manufacture is allowed to test the drug on human subjects. Prior research was conducted on animals.

<sup>11</sup> See Findlay, *supra* note 6. The four stages are: (I) safety, where clinical testing is conducted on a limited number of people to establish the safety of various doses; (II) efficacy, where the drug is tested for effectiveness on a small group of patients; (III) side-effects and long term use effects, where the drug is assessed for safety and effectiveness in wider clinical use; and (IV) post approval, where the drug company continues to test the newly-approved drug for adverse reactions and is obligated to report the nature and frequency of any reactions. *Id.*; see also Jeffrey & N. Gibbs & Bruce F. Mackler, *Food and Drug Administration Regulation and Products Liability: Strong Sword, Weak Shield*, 22 TORT & INS. L.J. 194, 204 (1987).

<sup>12</sup> See Findlay, *supra* note 6 (stating that phase I may take from 10 to 18 months; phase II may take from 21 to 35 months; phase III may take from 28 to 55 months).

<sup>13</sup> See generally 21 U.S.C. § 355(b) (1994); 21 C.F.R. §§ 56, 314 (2000).

<sup>14</sup> Carter, *supra* note 7, at 232.

<sup>15</sup> See 21 U.S.C. § 355(d) (1994); 21 C.F.R. § 314.50 (2000); see also Gibbs & Mackler, *supra* note 11, at 205.

<sup>16</sup> *Id.* (stating that companies often have to provide additional information to the FDA).

Once the drug receives approval from the FDA, the pioneer company may market it in the United States.<sup>18</sup> At this point, the pioneer company has expended a great deal of money on research in an effort to get this new drug approved for marketing.<sup>19</sup> The pioneer company, however, will quickly regain their investment through their exclusive sale of the drug.<sup>20</sup> The pioneer company will seek to retain exclusive control over the drug for as long as possible in order to maximize profits. To maintain exclusive control, the pioneer company uses several tactics to extend or manipulate the period of exclusivity it has been given.<sup>21</sup> To understand the period of exclusivity the pioneer company obtains, it is necessary to examine the patent of a pioneer pharmaceutical.

In general, a federal patent grants the patent holder the right to exclude others from using a patented invention for a twenty-year term from the date of filing.<sup>22</sup> "For products requiring government regulatory approval prior to marketing, such as drugs and medical devices, the length of the term often

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<sup>17</sup> *Id.* Another method is known as a "rolling" NDA, which speeds up the approval process. With a "rolling" NDA, the company does not file an application, but discusses the submission and resubmission with the FDA. When the company does file an NDA, it essentially has a perfect file, which the FDA can quickly approve. See Findlay, *supra* note 6, at 228. The average approval time for NDAs submitted in 1997 was 15 months. See Carter, *supra* note 7, at 234 (citing The FDA Modernization Act of 1997, Pub L. No. 105-115, available at <http://www.fda.gov/opacom/backgrounders/modact/htm> (last visited July 10, 2001)).

<sup>18</sup> See Carter, *supra* note 7, at 233. The drug may still be classified as a new drug for many years. Phase IV research takes place at this time. *Id.*

<sup>19</sup> See Michael P. VanHuysen, *Reform of the New Drug Approval Process*, 49 ADMIN. L. REV. 477, 478-79 (1997). In the United States, it takes between \$300 and \$500 million for a single drug to complete the FDA approval process. See *id.*; see also Stolberg & Gerth, *supra* note 1 (describing the tactics employed by designer drug companies to acquire patents).

<sup>20</sup> See HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY, Fig. 3 and accompanying text, available at <http://www.cbo.gov/showdoc.cfm?index=655&sequence=4&from=5> (last visited July 11, 2001).

<sup>21</sup> For example, designer drug companies have filed lawsuits for infringement, which under the Act prevents a generic drug company's application from being approved for 30 months. See Alfred E. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness? A Political, Legislative and Legal History of United States Law and Observations for the Future*, 39 J.L. TECH 389 (1999).

<sup>22</sup> 35 U.S.C. § 154(b) (1994). Recently, in 1995, the term was changed from 17 years to 20 years as a result of the Uruguay Round Agreements Act, Pub. L. No. 103-465, §532, 108 Stat. 4809 (1994) (codified at 35 U.S.C. § 301 (1994)).

is altered."<sup>23</sup> If the term were not altered, the patent would have substantially less value because the patent holder cannot sell its product during this approval period. This loss of patent protection as a result of regulatory delay is referred to as "front end distortion."<sup>24</sup> One of the purposes of the Hatch-Waxman Act was to remedy such distortions.<sup>25</sup> To reduce front-end distortion, the Act extended patent terms for products that are subject to regulatory delays for up to five years.<sup>26</sup>

### B. Generic Approval Process

A generic drug is a copy of a name brand drug whose patent or period of exclusivity has expired.<sup>27</sup> It typically costs much less than the brand name version.<sup>28</sup> The generic drug approval process varies greatly from that of new pioneer drugs. The Hatch-Waxman Act<sup>29</sup> is the leading legislation governing the generic drug approval process.<sup>30</sup> The Act serves two purposes:

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<sup>23</sup> David J. Bloch, *If It's Regulated Like a Duck...Uncertainties in Implementing the Patent Exceptions of the Drug Price Competition and Patent Term Restoration Act*, 54 FOOD & DRUG L.J. 111, 111 (1999).

<sup>24</sup> *Id.* at 112. There is also "back end distortion," another type of regulatory delay created by *Roche Products Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984). In *Bolar*, a competitor was not permitted to begin conducting testing until the competitor's patent had run. This had the effect of delaying a competitor for a period lasting as long as several years. *Id.*

<sup>25</sup> See Mossinghoff, *supra* note 7, at 188. "In 1978 President Carter launched a major domestic policy review on industrial innovation and that team recommended patent term restoration for pharmaceuticals and any other product that required regulatory review—to compensate for, or restore to the term of the patents time lost in regulatory review." *Id.* The result of this initiative was the Hatch-Waxman Amendment to the Food Drug and Cosmetic Act. See generally Engelberg, *supra* note 21 (outlining the events leading up to the passage of the amendment).

<sup>26</sup> See 35 U.S.C. § 156 (1994). This was done to "create a significant, new incentive which would result in increased expenditures for research and development, and ultimately in more innovative drugs." Ralph A. Lewis, *The Emerging Effects of the Drug Price Competition and Restoration Act of 1984*, 8 J. CONTEMP. HEALTH L. & POL'Y 361, 372-73 (1992) (quoting H.R. REP. NO. 98-857, 98th Cong., 2d Sess., pt 1, at 18, reprinted in 1984 U.S.C.C.A.N 2647, 2651). The Act also amended 35 U.S.C. § 271(e)(1) to prevent back end distortion. This amendment is called the "Bolar exemption." See *infra* note 51.

<sup>27</sup> See Justina A. Molzon, *The Generic Drug Approval Process*, 5 THE J. PHARMACY & L. 275, 275 (1995).

<sup>28</sup> See Lewis, *supra* note 26, at 366 (discussing how switching to a generic version of a drug can save a consumer thirty to fifty percent).

<sup>29</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 15 U.S.C. §§ 68b-68c, 70b (1994); 21 U.S.C. §§ 301, 355, 360cc (1994); 2201 (1994); 35 U.S.C. §§ 156, 271, 282 (1994)).

<sup>30</sup> Prior to 1984, when the Act was passed, there was no process for approving

(1) to "reduce health care costs by making generic drugs available more rapidly," and (2) to "foster new innovations in drug treatment by granting back patent protection for time lost during the process of drug approval by the Food and Drug Administration (FDA)."<sup>31</sup> In addition, the Act also had the effect of increasing competition.<sup>32</sup>

The generic drug development process begins by targeting a brand name drug whose patent is going to expire within three to five years.<sup>33</sup> A generic drug company may then submit an Abbreviated New Drug Application (ANDA) to the FDA as long as it has met the statutory criteria.<sup>34</sup> The ANDA must include information to essentially show that the new drug is already a "listed drug,"<sup>35</sup> "that the active ingredient of the new drug is the same as that of the listed drug,"<sup>36</sup> that the new drug will be administered in the same manner as the listed drug,<sup>37</sup> that the new drug is "bio-equivalent" to the listed drug,<sup>38</sup> and most

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generic drugs. Manufacturers had to follow the traditional drug approval process, which included filing an NDA and proving the safety and efficacy of the generic. *See Engelberg, supra* note 21, at 393. "The Act streamlined the approval process [for generics] by eliminating the need for sponsors to repeat duplicative, unnecessary, expensive and ethically questionable clinical and animal research to demonstrate the safety and efficacy of the drug product." Molzon, *supra* note 27, at 276.

<sup>31</sup> Reid, *supra* note 2, at 309; *see also* Mylan Pharm., Inc. v. Shalala, 81 F. Supp. 2d 30, 32 (D.D.C. 2000); H.R. REP. NO. 98-857, 98th Cong., 2d Sess., pt. 1, at 14, 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648.

<sup>32</sup> Since the enactment of the Act, the generic drug industry's prescription drug market share has increased from nineteen percent in 1984 to forty-three percent in 1996. *See Engelberg, supra* note 21, at 389-90; Lewis, *supra* note 26, at 365-66; Stolberg & Gerth, *supra* note 1, at 15.

<sup>33</sup> *See Findlay, supra* note 6, at 229. Some important aspects of the generic drug approval process include acquiring the active ingredient, developing a formulation, testing the product, and setting standards.

<sup>34</sup> *See* 21 U.S.C. § 355(j) (1994) (discussing the application and approval process for abbreviated new drug applications).

<sup>35</sup> *Id.* § 355(j)(2)(A)(i) (explaining that a listed drug has already been approved for safety and effectiveness).

<sup>36</sup> *Id.* § 355(j)(2)(A)(ii).

<sup>37</sup> *See* 21 U.S.C. § 355(j)(2)(A)(iii) (1994) (stating that new drugs will be administered in the same manner with the same dosage and strength).

<sup>38</sup> *Id.* § 355(j)(2)(A)(iv). A drug is considered bio-equivalent under ANDA if: (i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same . . . dose . . . ; or (ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same . . . dose . . . and the difference from the listed drug in the rate of absorption of the drug is intentional. . . .

importantly, the applicant must certify that "to the best of his knowledge," (1) there has been no patent filed for the listed drug, (2) that a patent has expired, (3) that the patent will expire on a certain date or (4) that the patent is invalid or will not be infringed by the new drug for which the application has been submitted.<sup>39</sup>

The generic drug approval process takes three to five years, provided there are no legal challenges.<sup>40</sup> The cost to a generic drug manufacturer is substantially less than that of a pioneer manufacturer.<sup>41</sup> Once the FDA has approved an ANDA, the generic drug company has a 180-day exclusivity period whereby no other generic company can market the generic version of the drug.<sup>42</sup> This 180 day exclusivity period can be triggered by the earlier of either: (1) the day that the applicant commences marketing the drug ("the commercial marketing trigger") or (2) the date of a decision of a court in a patent infringement suit holding that the patent which is the subject of the certification is invalid or not infringed, whichever is earlier.<sup>43</sup>

The generic approval process is seldom as simple and straightforward as it seems. Generic pharmaceutical companies face many obstacles before introducing a generic drug into the market. An example of one of these obstacles is the unnecessary interference by pioneer companies attempting to retain exclusivity over a drug. The next section examines these obstacles, and other ways generics fail to reach the drug market.

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*Id.* This is only a "safe harbor," and a company may prove bioequivalence in other ways. See *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995) ("The mere fact that Congress made the establishment of bioequivalence mandatory in the Act does not evidence an intent to limit the established testing practices of the FDA."); *Schering Corp. v. Sullivan*, 782 F. Supp. 645, 648-49 (D.D.C. 1992) ("There is simply no indication that the enumerated showings are the exclusive means for establishing bioequivalence.").

<sup>39</sup> 21 U.S.C. § 355(j)(2)(A)(vii). Patent infringement will be discussed in detail in Part I.D. of this Note.

<sup>40</sup> See Findlay, *supra* note 6, at 229. Legal battles that a generic company may face are discussed thoroughly in the next section of this Note.

<sup>41</sup> See Molzon, *supra* note 27, at 277-78. The generic drug approval process can be conducted at a "fraction of the cost of a large clinical study" that the pioneer company must go through. *Id.*

<sup>42</sup> See 21 U.S.C. 355(j)(4)(B)(iv); see also *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32-33 (D.D.C. 2000) (discussing the 180-day exclusivity period).

<sup>43</sup> 21 U.S.C. § 355(j)(5)(B)(iv). For a further discussion see John F. Resek, Comment, *Biovail v. Hoechst Aktiengesellschaft, Inc.: An Analysis Under the Sherman Act and the Noerr-Pennington Doctrine*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 571, 573 (2000).



### C. *Keeping the Generics Off the Market*

The stakes are very high for a pioneer drug company when its patent, and ultimately its exclusivity, is set to expire. Drug manufacturers work hard to maintain their market share in light of the severe ramifications that a loss of exclusivity can bring.<sup>44</sup> "Estimates from the Pharmaceutical Manufacturers Association (PMA) show that within one year after the expiration of a brand-name company's patent, thirty-five percent of the market is taken over by generic substitutes. This figure rises to fifty percent two years following patent expiration."<sup>45</sup>

### D. *Patent Infringement Suits*

Patent infringement is defined as making, using, offering to sell, or selling a patented invention without authority.<sup>46</sup> Under the Hatch-Waxman Act, however, determining an infringement is not as simple as it may sound.<sup>47</sup>

As discussed earlier in this Note,<sup>48</sup> when a generic drug manufacturer applies for an ANDA, it must certify, *inter alia*, that there is no patent for the listed drug, that the patent has expired, that the patent will expire, or that the patent is invalid or will not be infringed.<sup>49</sup> When a company makes a paragraph IV certification that the patent is invalid or will not be infringed

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<sup>44</sup> On the day of the ruling against Eli Lilly in determining the patent period of Prozac, Eli Lilly's stock plunged thirty-one percent, a loss of more than \$35 billion in market value. See *Ruling Speeds Generic Process; Eli Lilly Shares Drop; Pharmaceutical Co. Loses \$35 Billion in Market Value*, DALLAS MORNING NEWS, Aug. 10, 2000, at 10D. Analysts estimate that Eli Lilly will lose about \$1 billion a year in revenue once the generic is available. See Sharon Bernstein, *Ruling Could Help Speed Cheaper Generic Prozac; Pharmaceuticals: Eli Lilly is Stung by a Court Decision That Could Mean the Loss of \$1 Billion of Revenue a Year*, L.A. TIMES, Aug. 10, 2000, at C1. "Three months after Naprosene (R) went off-patent, its manufacturer, Syntax, lost 75% of its market to the generic brand." Mossinghoff, *supra* note 7, at 191.

<sup>45</sup> Melissa K. Davis, Note, *Monopolistic Tendencies of Brand-Name Drug Companies in the Pharmaceutical Industry*, 15 J.L. & COM. 357, 365 (1995). But see James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 468-69 (1986) (stating that a brand name manufacturer's market share is not greatly affected by the entrance of a generic into the market).

<sup>46</sup> See 35 U.S.C. § 271(a) (1994).

<sup>47</sup> See *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1567 (Fed. Cir. 1997) (noting that an action based solely upon the filing of an ANDA requires "a unique type of infringement analysis").

<sup>48</sup> See *supra* notes 33-39 and accompanying text.

<sup>49</sup> See *supra* note 39; see also 21 U.S.C. § 355(j) (1994).

it must then notify the patent holder, as listed in the Orange Book,<sup>50</sup> of such certification.<sup>51</sup> Once notified,<sup>52</sup> the patent holder

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<sup>50</sup> The Orange Book, published by the FDA, lists all of the patents and companies or individuals claiming to hold them. FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION AND RESEARCH, APPROVED PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (CCH 18th ed. 1998). This process is another result of the Hatch-Waxman Amendments. Before 1984, the FDA did not consider patents as a part of the drug approval process. The FDA does not evaluate whether the listed patents are valid, but presumes that the patents are valid. As a result, anyone can challenge the validity of a listed patent. See Elizabeth H. Dickinson, *Symposium Issue: Striking the Right Balance Between Innovation and Drug Price Competition: Understanding the Hatch-Waxman Act: FDA's Role in Making Exclusivity Determinations*, 54 FOOD & DRUG L.J. 195, 196 (1999) (noting that the FDA has been asked to look at the underlying patent claim, but refuses to because FDA personnel are not patent experts and do not have the technical expertise to make these assessments). A pioneer company often lists many patents for the same drug in the Orange Book in an attempt to discourage competition. They may include patents on the active ingredient the formulation of the drug, the tablet coating, the color of the pill, the bottle, and so on. Furthermore, a patent holder is permitted to list newly acquired patents on the eve of an ANDA approval. See Engelberg, *supra* note 21, at 418. Since the sole purpose of these patents is often to discourage competition, the Act says that no damages are to be awarded in the event that there is an actual infringement. See 35 U.S.C. § 271(e)(3) (1994). If there is an infringement, approval of the ANDA will be delayed until the end of the patented period. This assures the original filer the exclusivity period. See Dickinson, *supra* at 198. This is often referred to as the "bounty" provision. See Engelberg, *supra* note 21, at 405.

<sup>51</sup> See 21 U.S.C. § 355(j) (1994). The statute does not make it an act of infringement to use the patented drug while performing acts solely necessary for the preparation of the ANDA. See 35 U.S.C. § 271(e)(1) (1994) ("It shall not be an act of infringement to make, use, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under Federal law which regulates the manufacture, use, or sale of drugs . . .") (overruling *Roche Prod., Inc. v. Bolar Pharms. Co.*, 733 F.2d 858 (Fed. Cir. 1984)). This provision is referred to as the "Bolar exemption" and covers medical devices as well as drugs. See Bloch, *supra* note 23, at 113. The term "reasonably related" has been interpreted rather broadly to allow a substantial amount of use of a patented product without finding infringement. Some of the exempt activities include "collateral use of information," studies to evaluate the purity of the entity to be used in clinical trials, production of commercial scale batches of the product, and characterization studies. These activities would all be considered infringement without the Bolar exemption. Some things *not* reasonably related, and therefore infringing, include shipping of samples to foreign agencies and stockpiling. See Edward V. Filardi, *Symposium Issue—Striking the Right Balance Between Innovation and Drug Price Competition: Understanding the Hatch-Waxman Act: Patent Issues That Both Regulatory Affairs Personnel and Patent Attorneys Should Understand*, 54 FOOD & DRUG L.J. 215, 216–17 (1999).

<sup>52</sup> The process of notifying the patent holder of a paragraph IV certification has been problematic. The ANDA applicant must send notification by registered or certified U.S. Mail, return receipt requested. The ANDA applicant may not use other delivery services. See Dickinson, *supra* note 50, at 198.

has forty-five days to bring an action against the applicant for patent infringement.<sup>53</sup> If a patentee files a patent infringement suit, such suit suspends FDA approval until the earliest of the expiration of the patent, a judicial resolution of the correctness of the ANDA applicant's certification, or thirty months from the receipt of notice.<sup>54</sup> In essence, this is an incentive for a pioneer company to bring a patent infringement suit. Although the cost of patent litigation is high, thirty more months of exclusivity within the market is well worth the expense for many manufacturers.<sup>55</sup>

This has led to frivolous patent infringement suits by pioneer companies in an effort to retain market exclusivity over a drug for periods beyond their patents.<sup>56</sup> In order to successfully prove that a pioneer company's infringement suit is without merit, the generic company must demonstrate that the patent holder has baselessly asserted that it held objectively

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<sup>53</sup> See 35 U.S.C. § 271(e)(2) (1994); see also *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1563 (Fed. Cir. 1997).

<sup>54</sup> See 21 U.S.C. § 355(j)(5)(B)(iii) (1994); see also Engelberg, *supra* note 21, at 405. This period was originally eighteen months, but the time period was increased in the final version of the Act. H.R. REP. NO. 98-857, pt. 1, at 27 (1984). Patent litigation rarely ends before the 30-month period and the FDA may make the approval after the 30-month period. Most manufacturers, however, are unwilling to risk liability by bringing a generic drug product onto the market before the patent litigation is resolved. The thirty month provision was inserted to assure the pioneer manufacturer that its rights would not be taken away without proper adjudication. See *Glaxo*, 110 F.3d at 1569; see also Engelberg, *supra* note 21, at 405.

<sup>55</sup> See Resek, *supra* note 43, at 574; see also Engelberg, *supra* note 21, at 417 (stating that "[t]hese fees are nominal as compared to the hundreds of millions of dollars in monopoly profits that can be earned during the thirty months a competitor is held off the market"). The suit often involves a request for a declaratory judgment, in which there is an application to enjoin the allegedly infringing activity. To sustain a declaratory judgment, the party must show by a preponderance of the evidence that the defendant is engaged in infringing activity and there must be a refusal by the defendant to change course. See *Glaxo*, 110 F.3d at 1570.

<sup>56</sup> This is not to say that all infringement suits are frivolous. Pioneer companies often have real claims of infringement. Compare *Bristol-Meyer Squibb Co. v. Royce Labs.*, 69 F.3d 1130, 1137 (Fed. Cir. 1995) (finding that Royce's paragraph IV certification was incorrect, therefore finding an infringement) with *Fla. Breckenridge, Inc. v. Solvay Pharm.*, 174 F.3d 1227, 1236 (11th Cir. 1999) (finding that the infringement suit was frivolous, but refusing to award attorney's fees because both sides engaged in misleading conduct). "Despite the Congressional intent of promoting competition and decreasing drug costs via the drug approval process, aggressive strategies by innovator firms have resulted in an increase in the number of challenges filed against generic drugs." Molzon, *supra* note 27, at 280 (emphasis added) (footnote omitted).

greater patent coverage than that which was granted in the patent.<sup>57</sup>

In 1985, Pfizer brought a patent infringement suit against Chase, a generic drug manufacturer who was planning on marketing a generic version of Pfizer's Procardia.<sup>58</sup> Chase intended to market its version at a price thirty percent lower than that of Procardia. The two companies eventually settled out of court, but enough time had elapsed for Pfizer to develop and introduce a new and improved version of Procardia.<sup>59</sup> This enhanced version allowed Pfizer to maintain its control of the market for Procardia. Pfizer, however, succeeded in doing this through what was likely a baseless assertion of greater patent coverage.

Recently, in *Eli Lilly & Company v. Barr Laboratories, Inc.*,<sup>60</sup> the court declared that Eli Lilly did not have patent exclusivity over Prozac until 2003. Rather, the court determined that Eli Lilly had a double patent on Prozac, the second of which was invalid.<sup>61</sup> Therefore, the court determined that Eli Lilly's patent on Prozac should expire in 2001, making way for generics two years earlier than the company anticipated.<sup>62</sup> In essence, Eli Lilly had two patents on substantially the same claim.<sup>63</sup> Despite

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<sup>57</sup> See Davis, *supra* note 45, at 370 (citing Prof. Real Estate Investors v. Columbia Pictures Indus. Inc., 508 U.S. 49 (1993)). The lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. See Resek, *supra* note 43, at 581.

<sup>58</sup> See Davis, *supra* note 45, at 370; see also *FDA Approves Biovail's Procardia XL 30 mg Dosage*, 13 WORLDWIDE BIOTECH, Mar. 2001 (indicating that Procardia is used for the treatment of hypertension and angina).

<sup>59</sup> See Davis, *supra* note 45, at 370. The introduction of the new version enabled Pfizer to cushion the negative financial impact the generic entrance would have had on Pfizer. The new version of Procardia was an extended release form. See generally Victoria Slind-Flor, *Ulcer Drug Battle Erupts in Litigation*, NAT'L L.J., May 23, 1994, at A6 ("As its patent expires, Tagamet's maker files novel infringement suits against potential competitors.").

<sup>60</sup> 100 F. Supp. 2d 917, *rev'd in part, aff'd in part*, 222 F.3d 973 (Fed. Cir. 2000).

<sup>61</sup> A double patent is essentially two patents that are not patentably distinct. See *Eli Lilly & Co. v. Barr Lab.*, 222 F.3d at 984-85.

<sup>62</sup> The decision is on appeal. The U.S. Court of Appeals for the Federal Circuit has nationwide authority over patent cases and its decisions are rarely reversed. See *Ruling Speeds Generic Process; Eli Lilly Shares Drop; Pharmaceutical Co. Loses \$35 Billion in Market Value*, DALLAS MORNING NEWS, Aug. 10, 2000, at 10D.

<sup>63</sup> The judicially created doctrine of obviousness-type double patenting prohibits a party from obtaining an extension of exclusive rights through claims in a later patent that are not patently distinct from claims in an earlier patent. The purpose of it is to "prevent unjustified timewise extension of the right to exclude granted by a patent no matter how the extension is brought about." *Eli Lilly*, 222 F.3d at 985.

this obviousness, the court refused to comment as to whether the suit was frivolous.<sup>64</sup>

Courts are hesitant to find an infringement suit frivolous because the stakes of the case are so high.<sup>65</sup> Note, however, "[s]uch unilateral conduct on behalf of the patent holder would have a detrimental effect on competition in the market if the market participants were few in number."<sup>66</sup>

## II. ADMINISTRATIVE DELAY THROUGH THE FILING OF CITIZEN PETITIONS

Citizen petitions are an administrative step toward legal action against a generic manufacturer.<sup>67</sup> A citizen petition is the procedural tool used by innovator firms to protect their brand name products.<sup>68</sup> A citizen petition may be submitted by a pioneer manufacturer to initiate an administrative proceeding.<sup>69</sup> A party who files an administrative proceeding is requesting the FDA to "issue, amend, or revoke a regulation or order or take or

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The court found that Claim 1 of the Lilly's '895 patent, which pertains to a method of treating depression in humans by administering a compound (and then describing the formulation of the compound), and Claim 7 of the '549 patent, which claims a method for administering the compound fluoxetine hydrochloride, were essentially the same. Both claims relate to the same compound, and therefore the patents are essentially the same—the only difference was the wording. *See id.* at 985–87. The Court invalidated Claim 7 of the '549 patent, which was due to expire in 2003.

<sup>64</sup> The infringement suit helped Eli Lilly keep its exclusivity on Prozac while it was preparing for newer versions of the drug, which have separate patents, to become available. Eli Lilly is planning on releasing a once a week version of Prozac, and just recently released a version of Prozac that is patented to treat severe menstrual cramps in females. This drug is be marketed under the name Sarafem. *See* Melody Peterson, *Lilly Set Back in Patent Case Over Prozac*, N.Y. TIMES, Aug. 10, 2000, at C1. These drugs will help absorb the revenue loss when a generic version of Prozac becomes available. *See id.*

<sup>65</sup> *See* Merck & Co. v. Mylan Pharm., 79 F. Supp. 2d 552, 558 (E.D. Pa. 2000) ("Merck's infringement claim, albeit erroneous, was not baseless. Its course of conduct in pursuing the claim was neither vexatious, unusual nor disproportionate to the rather high stakes involved."). *See generally* Resek, *supra* note 43. The "high stakes" the court was referring to the millions of dollars at stake in both the litigation itself and the continued exclusivity of the patent. *Id.*

<sup>66</sup> Davis, *supra* note 45, at 371.

<sup>67</sup> *See* Molzon, *supra* note 27, at 280.

<sup>68</sup> *See id.* (finding that legal action can significantly delay the introduction of a generic drug as well as add to the costs of production); *see also* 21 C.F.R. § 10.30 (2000).

<sup>69</sup> *See* Molzon, *supra* note 27.

refrain from taking any other form of administrative action.”<sup>70</sup> A pioneer company may submit a citizen petition requesting increased testing to assure greater bioequivalence or safety.<sup>71</sup> The purpose of a pioneer manufacturer’s submission of a citizen petition may be to “create more difficult scientific and economic hurdles for generic firms to overcome.”<sup>72</sup> The petition is often submitted shortly before a pioneer’s product patent is due to expire.<sup>73</sup> In response, a generic firm may submit a citizen petition objecting to the requirements requested by the pioneer manufacturer.<sup>74</sup>

The FDA may respond to a citizen petition in one of three ways: it may approve the petition,<sup>75</sup> deny the petition,<sup>76</sup> or provide a tentative response, indicating why the agency has been unable to reach a decision on the petition.<sup>77</sup> Whichever decision the FDA reaches, the ultimate result is the same—delaying the approval of an ANDA in an attempt to extend the exclusivity period of a pioneer drug.

### III. COLLUSION BETWEEN PIONEER AND GENERIC DRUG COMPANIES

The Hatch-Waxman Act<sup>78</sup> served to decrease the market share that a pioneer drug has once its patent expires. “When the Act was passed in 1984, generic drug companies held eight percent of the market. By 1989, however, the generic drug companies’ market share had increased to thirty-three percent.”<sup>79</sup> This has led the companies to implement extreme measures to retain their market share. Pioneer companies

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<sup>70</sup> 21 C.F.R. § 10.30 (2000). An interested person, which the pioneer company is considered, may submit a citizen’s petition in the approval of an ANDA.

<sup>71</sup> See Molzon, *supra* note 27, at 281.

<sup>72</sup> *Id.*

<sup>73</sup> See *id.*

<sup>74</sup> See *id.*

<sup>75</sup> See 21 C.F.R. § 10.30(e)(2)(i) (2000).

<sup>76</sup> *Id.* § 10.30(e)(2)(ii).

<sup>77</sup> *Id.* § 10.30(e)(2)(iii).

<sup>78</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub L. No. 98-417, 98 Stat. 1585 (1984) (codified at 15 U.S.C. §§ 68b–68c, 70b (1994); 21 U.S.C. §§ 301, 355, 360cc (1994); 28 U.S.C. 2201 (1994); 35 U.S.C. §§ 156, 271, 282 (1994)).

<sup>79</sup> Davis, *supra* note 45, at 365. There are other factors that contributed to this increase, including the expiration of a large number of patents on widely prescribed drugs during this period. See *id.*

collude with generics as a market control strategy to prevent competition.<sup>80</sup>

Four drug companies have recently come under fire for delaying the sale of generic drugs.<sup>81</sup> The companies involved are Andrx Corporation and Hoechst A.G., for a deal involving Cardizem, and Abbott Laboratories and Geneva Pharmaceuticals, for a deal involving Hytrin.<sup>82</sup> They are accused of entering into agreements wherein the pioneer company would pay the generic company in exchange for not releasing the generic version of the drug, enabling the pioneer to keep its market share.<sup>83</sup> These tactics may violate antitrust laws by substantially reducing competition and creating monopolies.<sup>84</sup>

In 1998, Abbott Laboratories, the manufacturer of Hytrin, a brand name high blood pressure medication, entered into an agreement with Geneva Pharmaceuticals, a generic drug maker seeking to market terazonin, a generic version of Hytrin.<sup>85</sup> Under the terms of the agreement, Abbott would pay Geneva \$4.5 million a month not to produce the generic version of the drug.<sup>86</sup> A similar deal was struck between Andrx and Hoechst A.G. over the generic version of Cardizem CD, one of the nation's top-selling heart drugs.<sup>87</sup> Hoechst agreed to pay Andrx \$100 million a year to withhold the release of its generic version of the drug.<sup>88</sup> Fear of antitrust investigation forced these companies to abandon the agreements.<sup>89</sup>

The Federal Trade Commission (FTC) filed complaints against these companies regarding the delays.<sup>90</sup> In *In Re*:

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<sup>80</sup> See *id.* at 357.

<sup>81</sup> See Peterson, *supra* note 64, at C8.

<sup>82</sup> See *id.*

<sup>83</sup> See *id.*

<sup>84</sup> See Davis, *supra* note 45, at 357.

<sup>85</sup> See Petersen, *supra* note 81.

<sup>86</sup> See Stolberg & Gerth, *supra* note 1, at 1. This was not the first such deal made by Abbott. The day before the deal with Geneva, Abbott made a similar deal with Zenith Goldline Pharmaceuticals. To settle out of patent court, Abbott agreed to pay Zenith \$2 million a month, up to a maximum of \$42 million.

<sup>87</sup> See Petersen, *supra* note 64.

<sup>88</sup> See *id.*

<sup>89</sup> See *id.* The generic version of Hytrin became available in August 1999, more than a year after Geneva's ANDA was approved. After the deal was dissolved, Geneva successfully defended a patent infringement case brought by Abbott. See *Abbott Lab. v. Geneva Pharm.*, 182 F.3d 1315, 1318 (Fed. Cir. 1999).

<sup>90</sup> The matter between Geneva and Abbott was handled administratively. The complaints are available online at <http://www.ftc.gov/os/2000/05/abbott>

*Cardizem CD Antitrust Litigation*,<sup>91</sup> the court found that the agreement between Hoechst and Andrx was an unreasonable restraint of trade and was *per se* invalid under § 1 of the Sherman Antitrust Act.<sup>92</sup>

The essential elements of a violation of § 1 of the Sherman Act include a (1) contract, combination, or conspiracy, (2) which affects interstate commerce and (3) imposes an “unreasonable” restraint on trade.<sup>93</sup> The courts use two methods to analyze whether an agreement is a violation of the Act. The first method is a *per se* approach, the second is a rule of reason approach.<sup>94</sup> A *per se* approach is used if the agreement involves practices, such as horizontal price fixing among competitors, which are inherently anti-competitive.<sup>95</sup> Such agreements are considered *per se* invalid without an inquiry into the actual harm caused.<sup>96</sup> The court in *In Re: Cardizem* determined that the agreement was horizontal<sup>97</sup> and thus *per se* invalid. In other words, the court found that the agreement between Hoechst and Andrx restricted competition, allocated the entire U.S. market for Cardizem and its bioequivalent to Hoechst, and allowed Hoechst to maintain or fix the price of Cardizem at a non-competitive level during the life of the agreement.<sup>98</sup>

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genevacomp.htm (last visited October 1, 2000).

<sup>91</sup> 105 F. Supp. 2d 682 (E.D. Mich. 2000).

<sup>92</sup> See *id.* at 706. Congress passed the Sherman Antitrust Act in 1890. It is a broad statute enacted to promote competition by suppressing monopolistic trade practices. See 54 AM. JUR. 2D Monopolies, Restraints of Trade, and Unfair Trade Practices § 1 (1996).

<sup>93</sup> *In Re: Cardizem*, 105 F. Supp. 2d at 692 (quoting *White & White, Inc. v. American Hosp. Supply Corp.*, 723 F.2d 495, 504 (6th Cir. 1983)).

<sup>94</sup> See *In Re: Cardizem*, 105 F. Supp. 2d at 692. The “rule of reason” approach asks the fact finder to decide whether under all of the circumstances of the case the restrictive practice imposes an unreasonable restraint of trade. See *id.* (quoting *Betkerur v. Aultman Hosp. Ass’n*, 78 F.3d 1070, 1088 (6th Cir. 1996)).

<sup>95</sup> See *id.* “An agreement is illegal *per se* when the restraint of trade has no legitimate justification, lacks any redeeming competitive purpose and ‘would always or almost always tend to restrict competition and decrease output.’” *Resek, supra* note 43, at 578.

<sup>96</sup> See *id.* at 579. “When an alleged agreement is illegal *per se*, no facts need be proven beyond the making of an agreement.” *Id.*

<sup>97</sup> “An arrangement is said to be horizontal when (1) its participants are *either* actual rivals at the time the agreement is made or (b) potential rivals at the time the agreement is made; *and* (2) the agreement eliminates some avenue of rivalry among participants.” *In re: Cardizem*, 105 F. Supp. 2d at 700 (quoting 11 H. Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, P 1901 at 185 (1998)).

<sup>98</sup> See *In re: Cardizem*, 105 F. Supp. 2d at 705.



This agreement prevented any other generic manufacturers from marketing a generic version of Cardizem. Biovail, another generic manufacturer, filed an ANDA with the FDA but was prevented from obtaining preliminary FDA approval because Andrx's 180 day exclusivity period had not yet been triggered and therefore had not expired.<sup>99</sup> Andrx's exclusivity period had not yet expired because under the agreement between Hoechst and Andrx, Andrx would not market the drug, so there would be no "commercial marketing trigger," and there was no patent litigation, so there would be no "court decision trigger."<sup>100</sup> The agreement, had it continued, would have essentially prevented a generic version of Cardizem from being available at market.<sup>101</sup>

#### IV. POSSIBLE REFORMS TO THE HATCH-WAXMAN ACT

One of the most common complaints about the Hatch-Waxman Act involves the drafting of the Act.<sup>102</sup> Those who have commented on the drafting have labeled it "vague," "complicated," and "unclear."<sup>103</sup> This inelegant drafting has led to a number of problems applying the Act and effectuating its purpose.<sup>104</sup> These problems need to be addressed to ensure that consumers have speedy access to generic drugs once the patent on the brand name has expired. Congress has realized that there are problems and loopholes in the statute that must be addressed, and the 106th Congress has proposed a bill to address some of these problems.<sup>105</sup>

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<sup>99</sup> See *Biovail v. Hoechst Aktiengesellschaft, Inc.*, 49 F. Supp. 2d 750, 757 (D.N.J. 1999).

<sup>100</sup> See *Resek*, *supra* note 43, at 575.

<sup>101</sup> The next section of this Note discusses the problems associated with the 180-day exclusivity period, as well as proposed reforms to this period.

<sup>102</sup> See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990). Justice Scalia opined that "[n]o interpretation we have been able to imagine can transform . . . [it] into an elegant piece of statutory draftsmanship." *Id.* at 679. He went on to explain that the statute is "not plainly comprehensible on anyone's view." *Id.* at 669; see also *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1069 (D.C. Cir. 1998) (quoting other courts referring to the Act as "cumbersome" and "very confusing and ambiguous").

<sup>103</sup> Part of the reason that it is so confusing is that it is a compromise between the pioneer companies and the generic companies. "A combination of mutual mistrust and fears about the uncertain economic impact of making generic drugs more readily available led to the creation of a law which was inelegantly drafted and extremely complex." Engelberg, *supra* note 21, at 391-92 (footnote omitted).

<sup>104</sup> See *id.*

<sup>105</sup> See H.R. 5247, 106th Cong., 2d Sess. (2000). The bill is to be cited as the

### A. 180-Day Exclusivity Period

The biggest problem in effectuating the purposes of the Hatch-Waxman Act has been the 180-day exclusivity period granted to the first generic manufacturer to file an ANDA.<sup>106</sup> The Act provides two “trigger” points for the beginning of the exclusivity period—a “commercial marketing” trigger and a “court decision” trigger.<sup>107</sup> Applying the statute, the FDA believed that the period was triggered by the first substantially complete ANDA with a paragraph certification challenging the patent *and* had to successfully defend the patent suit brought by the innovator drug company.<sup>108</sup> In *Mova Pharm. Corp. v. Shalala*,<sup>109</sup> however, the United States Court of Appeals changed this interpretation.<sup>110</sup>

The court in *Mova Pharm. Corp.* found that the FDA’s interpretation of the statute imposed a “successful defense requirement,” which was not what Congress had intended in drafting the statute.<sup>111</sup> Subsequent to *Mova Pharm. Corp.*, the FDA issued a guidance document interpreting the statute to say that one need not be sued to obtain exclusivity.<sup>112</sup> This provision of the Act should be amended<sup>113</sup> to make it clear that an applicant who makes a paragraph IV certification *need not* successfully defend a patent infringement suit in order to trigger the exclusivity period.

The interpretation of the term “court” in the court decision trigger of the exclusivity period is yet another problem in the statute.<sup>114</sup> Which court decision triggers the exclusivity period? The district court? The court of appeals? The Supreme Court?

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“Greater Access to Affordable Pharmaceuticals Act” or the “GAAP Act of 2000.”

<sup>106</sup> See Dickinson, *supra* note 50, at 199.

<sup>107</sup> See Resek, *supra* note 43, at 575.

<sup>108</sup> See Dickinson, *supra* note 50, at 199.

<sup>109</sup> 140 F.3d 1060 (D.C. Cir. 1998).

<sup>110</sup> See *id.* at 1066.

<sup>111</sup> *Id.* The court noted that the FDA’s interpretation would lead to bizarre results in (1) cases where the first ANDA applicant is not sued, and (2) cases in which the first ANDA applicant loses its suit.

<sup>112</sup> See FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY—180-DAY GENERIC DRUG EXCLUSIVITY UNDER THE HATCH-WAXMAN AMENDMENTS TO THE FEDERAL FOOD, DRUG, & COSMETIC ACT 63 Fed. Reg. 37890 (June 1998).

<sup>113</sup> See 21 U.S.C. § 355 (j)(5)(B)(iv) (1994).

<sup>114</sup> Currently, 21 U.S.C. § 355 (j)(5)(B)(iv)(II) states that the period is triggered on “the date of a decision of a court . . . holding the patent which is the subject of the certification to be invalid or not infringed.” *Id.* (emphasis added).

Two cases have addressed this issue and determined that the word "court" should be interpreted as the first court that finds the patent in question to be invalid, unenforceable, or not infringed.<sup>115</sup> The proposed bill has not adopted these versions<sup>116</sup> and states that "court" means a court "from which no appeal can or has been taken."<sup>117</sup>

The last problem of the 180-day exclusivity period is the situation that occurred in *In re: Cardizem*<sup>118</sup> and a problem that Judge Wald warned against in *Mova*.<sup>119</sup> If a generic manufacturer colludes with a pioneer manufacturer and never markets the drug or defends a patent litigation suit, the exclusivity period may never be triggered. There must be a safeguard in the statute to prevent this restraint of trade and to ensure that the period will be triggered.<sup>120</sup> The proposed legislation has addressed this problem by amending the trigger provisions of the act to state that "if the (paragraph IV). . .applicant fails to commence commercial marketing of its drug product once its application is made effective . . ." the period will become available to the next generic applicant.<sup>121</sup> This amendment will hopefully serve as a disincentive for both generic and pioneer drug manufacturers to collude.

### B. Frivolous Patent Infringement Suits

The fear in imposing sanctions for frivolous lawsuits is that the cost of the sanction will either be passed down to the consumer, further increasing health costs, or, in the alternative, will have the effect of decreasing the essential research conducted by the pioneer companies. There is no simple answer to this problem. Stays should be determined on a case-by-case basis. There should not be an automatic 30-month stay. An

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<sup>115</sup> See *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30 (D.D.C. 2000).

<sup>116</sup> See H.R. 5247, 106th Cong., 2d Sess. (2000).

<sup>117</sup> *Id.*

<sup>118</sup> See *In re: Cardizem*, 105 F. Supp. 2d at 682, 686 (E.D. Mich. 2000); see also *supra* notes 90–98 and accompanying text.

<sup>119</sup> See *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998).

<sup>120</sup> The Coalition for Pharmaceutical Reform has been urging a reform of the 180-day exclusivity period. See *Driving Up Drug Prices*, N.Y. TIMES, July 26, 2000, at A22. The FTC proposed that the companies should be forced to pay the amount of income generated as a result of the increased prices. Some have called this approach "unusual" and "aggressive" but it may be an effective deterrent. See Reid, *supra* note 2, at 338.

<sup>121</sup> H.R. 5247, 106th Cong., 2d Sess. (2000).

examination of the merits should determine the length of the stay, if any is to be granted. Perhaps there should also be a good faith requirement for pioneer companies filing patent infringement suits. There have been proposals that suggest that those who have been convicted of illegal activities relating to development or approval should be banned from submitting drug applications.<sup>122</sup> Opponents to these proposals argue that it is exclusively directed at the generic drug industry and that it will effectively deprive consumers of life-saving drugs.<sup>123</sup> While these suggestions may help, there is no definitive answer. The importance of pharmaceuticals in this country leaves many citizens at the mercy of these manufacturers.

The FTC has proposed a study to examine both the 30-month stay and the 180-day marketing exclusivity period.<sup>124</sup> The focus of the study would be to see whether these provisions of the Act have encouraged generic competition or facilitated the use of anti-competitive strategies.<sup>125</sup>

### C. *Citizen Petitions*

Pioneer drug companies should be prevented from filing Citizen Petitions relating to the approval of an ANDA. These petitions should be reserved for those who have a non-commercial interest in the drug. The proposed legislation would amend 21 U.S.C. § 355(j)(5) to include a provision stating that the filing of a Citizen Petition “shall not . . . delay review and approval of [an ANDA,]” unless the petition demonstrates that approval would pose a threat to public health and safety.<sup>126</sup>

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<sup>122</sup> See H.R. 4810, 101st Cong., 2d Sess. (1990).

<sup>123</sup> See Lewis, *supra* note 26, at 377.

<sup>124</sup> See Press Release: FTC to Study Generic Competition, Oct. 11, 2000, available at <http://www.ftc.gov/opa/2000/10/genericdrug.htm> (visited July 12, 2000).

<sup>125</sup> See *id.*

<sup>126</sup> H.R. 5247, 106th Cong., 2d Sess. (2000).

## CONCLUSION

The Hatch-Waxman Act has been effective.<sup>127</sup> Once hailed as the "most important consumer bill of the decade,"<sup>128</sup> the Act has helped consumers have greater access to cheaper, generic versions of life-saving drugs.<sup>129</sup> More *can* be done. As loopholes in the Act emerge, Congress must take action to ensure that the public is not being cheated.<sup>130</sup> The proposed legislation by Congress, as well as the proposed study by the FTC, are both comprehensive measures that can benefit consumers.

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<sup>127</sup> The 1996 Senate Judiciary Committee Hearings declared that the Act was healthy. Generic drug industry representatives claimed that the Act "isn't broke" and "doesn't need fixing." A noted economist stated that "in terms of facilitating generic competition, the Act had clearly been a tremendous success." There was criticism however of the act by the pioneer industry. See *Pharmaceutical Patent Issues: Interpreting GATT: Hearings on S. 1277 Before the Senate Judiciary Comm.*, 104th Cong. (1996) (Statement of John Klein, Chairman, Generic Pharmaceutical Industry Ass'n.); see also Lewis, *supra* note 26, at 377; Reid, *supra* note 2, at 331.

<sup>128</sup> S. REP. NO. 104-394, 104th Cong., 2d Sess. (1996) (report submitted by of one of the original sponsors of the Act, Sen. Orrin Hatch).

<sup>129</sup> See *GphA Reports Consumers Will Save \$100 Billion Through Improved Access to Generic Pharmaceuticals*, U.S. NEWSWIRE, Sept. 19, 2000. A "report by the Managed Care Institute of Samford University states that every one percent increase in generic drug utilization results in savings of \$1.16 billion." *Id.*

<sup>130</sup> See Congressional Press Release, *Generic Medicine More Accessible*, Sept. 27, 2000.